

K040204/S-CI

510(k) PREMARKET NOTIFICATION
Zyoptix™ XP Microkeratome

MAR 22 2004

510(k) SUMMARY

FOR

Zyoptix™ XP Microkeratome

1. SUBMITTER INFORMATION

Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609

Contact Person: Debra Ketchum
Manager, Regulatory Affairs
Telephone No.: (585) 338-8638
Fax No.: (585) 338-0702

2. DEVICE NAME

Classification Name: Keratome

Proprietary Name: Zyoptix™ XP Microkeratome

3. PREDICATE DEVICES

Hansatome® Excellus™ Microkeratome

K021640

4. DESCRIPTION OF DEVICE

The Zyoptix™ XP Microkeratome is an automated pivoting keratome that is connected to, and controlled by a console. An oscillating cutting blade is moved across the cornea in a very precise path by the translational drive mechanism to create a hinged corneal flap of a predetermined diameter and thickness. The same options are available with the Zyoptix™ XP Microkeratome as with the Hansatome® Excellus™ Microkeratome including flap depths of 160, 180 and 200 microns with either an 8.5 mm or 9.5 mm flap diameter, and two sizes of suction rings, a 19 mm and 20 mm suction ring. The device is designed to share the same functional cutting geometry, and suction ring-to-eye interface geometry as the Hansatome® Excellus™ Microkeratome.

The translation drive has been changed from a rack and pinion gear drive to a two-link pivot mechanism that provides an identical motion. Corresponding modifications have been made to cutting head and suction ring that supports the two-link drive mechanism. The new cutting head is also easier for the operator to change. Additionally, the component parts were designed for ease of manufacture, assembly, interchangeability, and improved reliability.

The Zyoptix™ XP Blade is produced by a more exacting manufacturing process and is designed to be used exclusively with the Zyoptix™ XP Microkeratome. The improved manufacturing process reduces the tolerance of blade extension variation. An analysis of the dimensional specifications based on 3-D CAD Modeling (3 dimensional computer aided design) established that the average thickness of the corneal flap produced by the Zyoptix™ XP Microkeratome and the Hansatome® Excellus™ Microkeratome are equivalent.

5. INDICATIONS FOR USE

The Bausch & Lomb Zyoptix™ XP Microkeratome is a precision-manufactured instrument indicated for creating a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

6. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE

The Medical Devices Risk Analysis applies to the changes made from the existing Hansatome® Excellus™ Microkeratome to the proposed Zyoptix™ XP Microkeratome. The analysis concluded there are no unacceptable risks known.

7. SUBSTANTIAL EQUIVALENCE

Substantial Equivalence Summary Table

SIMILARITIES

Characteristics	<u>Current Hansatome Excellus Microkeratome</u>	<u>Proposed Zyoptix XP Microkeratome</u>
Intended Use	Lamellar resection of the cornea preceding LASIK surgery or other treatment requiring initial lamellar resection of the cornea	Lamellar resection of the cornea preceding LASIK surgery or other treatment requiring initial lamellar resection of the cornea
Operating Principle	Electrically driven oscillating blade housed in a head, which guides the blade across the cornea within controlled parameters.	Electrically driven oscillating blade housed in a head, which guides the blade across the cornea within controlled parameters.
Patient contact portion	<ul style="list-style-type: none">• Suction Ring• Microkeratome Head• Blade	<ul style="list-style-type: none">• Suction Ring• Microkeratome Head• Blade
Materials	<ul style="list-style-type: none">• Suction ring• Microkeratome Head• Blade <ul style="list-style-type: none">• Stainless Steel• Stainless Steel• Low Carbon Stainless steel	<ul style="list-style-type: none">• Stainless Steel• Stainless Steel• Low Carbon Stainless steel
Keratome Mechanism	<ul style="list-style-type: none">• Suction ring• Microkeratome head thickness plate• Electric motor• Control mechanism• Cutting Principle <ul style="list-style-type: none">• Single port annular suction fixation• 3 interchangeable heads with fixed thickness• DC powered 6 to 9 volts• Footswitch• Blade oscillation	<ul style="list-style-type: none">• Single port annular suction fixation• 3 interchangeable heads with fixed thickness• DC powered 6 to 9 volts• Footswitch• Blade oscillation

DIFFERENCES

Characteristics	<u>Current Hansatome Excellus Microkeratome</u>	<u>Proposed Zyoptix XP Microkeratome</u>
Components	Matched	Interchangeable
Left/Right Procedure Set-Up	Left/Right Adaptor	Selector Switch
Gear Box	Hand built gearbox	Integrated motor and gearbox
Head to Hand piece Interface	Screws into head	Snaps into head
Translation Drive	Rack and pinion	Two-link pivot mechanism

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Substantial Equivalence

The Zyoptix™ XP Microkeratome is substantially equivalent to the Hansatome® Excellus™ Microkeratome cleared in the Premarket Notification K021640 on June 19, 2002.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 22 2004

Bausch & Lomb Surgical, Inc.
c/o Debra L. B. Ketchum
Manager Global Regulatory Affairs
1400 N. Goodman Street
Rochester, NY 14609

Re: K040204

Trade/Device Name: Zyoptix™ XP Microkeratome
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: HNO
Dated: March 2, 2004
Received: March 3, 2004

Dear Ms. Ketchum:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609

Indications for Use Statement

510(k) Number (if known):

K040204

Device Name: Zyoptix™ XP Microkeratome

Indications for Use:

The Zyoptix™ XP Microkeratome is a precision-manufactured instrument indicated for use in creating a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use

OR

Over-The-Counter-Use _____

MAB initials

(Division Sign-Off)

Division of Ophthalmic Ear,
Nose and Throat Devices

510(k) Number K040204